

REMARKS

Many claims have been cancelled without prejudice in an effort to further prosecution.

The invention, as claimed in the remaining independent claims 10 and 79, relates treating a metallic bone implant by treating the implant with a solution containing fluoride atoms in the specified concentration solution or with hydrofluoric acid (HF) in a specified concentration range. As noted in the specification at 7, this treatment promotes the strength of attachment of permanent implants in bone and reduces the time it takes to achieve strong bonds. The independent claims recite that the process "consists essentially of" the recited step. From the discussion of examples at page 10, it is seen that implants are merely cleaned before the HF treatment and are merely washed with water and placed in a sterile package to await surgical implantation following the treatment. Thus, the "consisting essentially of" transitional phrase appropriately recites the HF step as the only significant one. Independent claim 10 has been amended to recite that the solution is of a fluoride from the group consisting of lithium fluoride, cesium fluoride, potassium fluoride, ammonium fluoride, stannous fluoride, or any combination thereof. Support for this amendment is at page 5, lines 5-9 and page 6, lines 10-16 of the application. Independent claim 79 recites treating with 0.01% to 0.5% hydrofluoric acid.

Independent claim 10 stands rejected as anticipated by JP 3146679.

JP 3146679 describes a two-step treatment of an implant surface involving (the references to pages and lines are given in relation to the English translation submitted in the parent application):

- (i) immersion in an aqueous solution of 1-6% (w/w) hydrofluoric acid (HF), followed by
- (ii) immersion in a mixed solution of 1-6% (w/w) hydrofluoric acid (HF) and 1-10% (w/w) hydrogen peroxide (H₂O₂) (page 3).

JP does not disclose or suggest the use of lithium fluoride, cesium fluoride, potassium fluoride, ammonium fluoride or stannous fluoride, and the subject matter of amended claim 10 accordingly is not anticipated or rendered obvious by JP 3146679, and claim 10 is allowable over JP 3146679 under 35 USC 102(b) and 103(a).

Independent claim 79 (reciting 0.01% to 0.5% hydrofluoric acid) stands rejected as obvious in view of JP 3146679. In the office action it was stated:

[I]t would be obvious to modify Haruyuki [JP 3146679] by using different concentrations because same were known to be cause effective variables and routine experimentation would have been expected to optimize them.

Furthermore, Haruyuki teaches that indicates that feature with an average depth below 0.5 μm would have a small anchoring effect (Page 4 Lines 21-26). This statement suggests that there is some improvement in implant-adhesion at HF concentrations below 1%.

One of ordinary skill in the art would have been motivated at the time of invention to use a concentration less than 1% to determine the point at which adhesion is improved over the adhesion produced without treatment.

Applicants respectfully disagree with these statements about what is suggested by JP 3146679 and instead assert that treatment at concentrations less than 1% are contraindicated by JP 3146679

Treatment with a hydrofluoric acid (HF) solution having a concentration $<1\%$ is in JP 3146679 said to be undesirable since:

- "pore sizes $\geq 1\mu\text{m}$ cannot be reached at below 1%" (page 4, col. 1, lines 12-13),
- "the adhesive strength to cells is low when the average pore size is below 1 μm " (page 4, col. 1, lines 14-16), and
- "the anchoring effect between the bone and the biorepair member is low at an average depth below 0.5 μm " (page 4, col. 1, lines 24-26).

Furthermore, it is also stated that "shallow depressions" are undesirable for the following reason:

- "the depressions are too shallow at below 30 seconds, which strongly impairs satisfactory removal of the contaminating layer present prior to treatment" (page 4, col. 1, lines 33-36).

Furthermore, in the prior art description of JP 3146679 it is stated that:

- “when, for example, the surface is a mirror surface lacking elevations and depressions, the bonding strength is weak and the member will not be adequately supported by the tissue” (page 2, col. 2, lines 31-34), and

- “the bonding force with cells is still not always adequate” for implants having “ultrafine” (0.01-1 μm) “pores in the surface” (page 3, col. 1, lines 18-23).

JP 3146679 thus clearly teaches:

- (i) that treatment with HF having a concentration less than 1% provides pore sizes below 1 μm , and
- (ii) an implant surface comprising pore sizes below 1 μm gives an inadequate anchoring effect and is thus not desirable.

Therefore, the skilled man would have no reason to further explore the treatment with <1% HF, because “the point at which adhesion is improved over the adhesion produced without treatment” (the examiner’s words) was already considered to be known to be a value above 1%. Contrary to the statements in the office action, nothing in JP 3146679 suggests that there is “some improvement in implant adhesion at HF concentrations below 1%.”

The unexpected result according to the invention of the present invention is that the content of fluorine and/or fluoride on the implant surface seems to be at least equally important, or even more important, in view of bonding strength than the implant surface roughness. The results described in the application indicate that the best effects are obtained when the implant surface morphology is unaffected or only slightly affected.

The treatment according to the invention not only provides an **adequate bonding strength** but **also** an **improved rate of bone tissue attachment** (page 4, lines 29-31). In the Background section of this application, etching is said to provide relatively large surface irregularities, and “although the retention may be improved, the time necessary for the osseointegration process may be longer since the bone tissue would have to grow into the irregularities in the surface” (page 2, lines 22-24).

The subject matter of claim 79 accordingly is nowhere suggested by JP 3146679, and claim 79 is allowable under 35 USC 103(a).

The remaining claims depend on claim 10 or 79 and are allowable with them.

Accordingly, all claims are submitted to be in condition for allowance.